



PTO/SB/08a (05-07)

Approved for use through 09/30/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10611582
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name		
Attorney Docket Number	065478-0205	

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4554276		2007-10-17	LaMattina	
	2	4676984		1987-06-30	Wu et al.	
	3	4757060		1988-07-12	Lukacsko et al.	
	4	4766117		1988-08-23	Crawford et al.	
	5	4853230		1988-11-22	Lovgren et al.	
	6	5037815		1991-08-06	Lukacsko et al.	
	7	5071643		1991-12-10	Yu et al.	
	8	5204118		1993-04-20	Goldman et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10611582
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name		
Attorney Docket Number	065478-0205	

	9	5417980		1995-05-23	Goldman et al.	
	10	5629013		1997-05-13	Upson et al.	
	11	5753265		1998-05-19	Bergstrand et al.	
	12	5763422		1998-06-09	Lichtenberger et al.	
	13	5817338		1998-10-06	Bergstrand et al.	
	14	5955451		1999-09-21	Lichtenberger et al.	
	15	5972389		1999-10-26	Shell et al.	
	16	6015801		2000-01-18	Daifotis et al.	
	17	6024222		2000-02-15	Friberg et al.	
	18	6090827		2000-07-18	Erickson et al.	
	19	6160020		2000-12-12	Ohannesian et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10611582
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit		1615
Examiner Name		
Attorney Docket Number		065478-0205

	20	6183779		2001-02-06	Ouali et al.	
	21	6365184		2002-04-02	Depui et al.	
	22	6392525		2002-05-21	Kato et al.	
	23	6544556		2003-04-08	Chen et al.	
	24	6613354		2003-09-02	Depui et al.	
	25	6759935		2004-07-06	Moro et al.	
	26	4786505		1998-11-22	Lovgren et al.	
	27	5464632		1995-11-07	Cousin et al.	
	28	6299904		2001-10-09	Shimizu et al.	
	29	6328994		2001-12-11	Shimizu et al.	
	30	6489346		2002-12-02	Phillips et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10611582
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	
Attorney Docket Number	065478-0205

31	6183776		2001-02-06	Depui et al.	
32	6096340		2000-08-10	Chih-Ming Chen et al.	
33	5750104		1998-05-12	Sipos	
34	6328993		2001-12-11	Linder et al.	
35	5312818		1994-05-17	Rubin et al.	
36	6013281		2000-01-11	Lundberg	
37	6258845		2001-07-01	Gerner	
38	5952021		1999-09-14	Santus	
39	6800307		2004-10-05	Matthews et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
-------------------	---------	--------------------	------------------------	------------------	---	--

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10611582
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name		
Attorney Docket Number	065478-0205	

1	20020051814		2002-05-02	Chen	
2	20020051814		2002-05-02	Chen	
3	20020045646		2002-04-18	Phillips	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² j	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	85/03443	WO		1985-08-15	Sunshine et al.		<input type="checkbox"/>
	2	93/12517	WO		1993-06-24	Fujushita et al.		<input type="checkbox"/>
	3	95/32957	WO		1995-12-07	Von Unge		<input type="checkbox"/>
	4	96/01623	WO		1996-01-25	Bergstrand et al.		<input type="checkbox"/>
	5	96/01625	WO		1996-01-25	Bergstrand et al.		<input type="checkbox"/>
	6	96/07421	WO		1996-03-14	Satoh		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10611582
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name		
Attorney Docket Number	065478-0205	

7	96/22780	WO		1996-08-01	Lichtenberger et al.		<input type="checkbox"/>
8	96/24375	WO		1996-08-15	Depui et al.		<input type="checkbox"/>
9	97/25064	WO		1997-07-17	Depui et al.		<input type="checkbox"/>
10	97/25066	WO		1997-07-17	Depui et al.		<input type="checkbox"/>
11	98/11879	WO		1998-03-26	Shell et al.		<input type="checkbox"/>
12	98/13073	WO		1998-04-02	Lichtenberger et al.		<input type="checkbox"/>
13	98/50033	WO		1998-11-12	Lundy et al.		<input type="checkbox"/>
14	99/01000	WO		1999-01-07	Jokinen		<input type="checkbox"/>
15	99/12524	WO		1999-03-18	Skinhoh et al.		<input type="checkbox"/>
16	99/39700	WO		1999-08-12	Esposito et al.		<input type="checkbox"/>
17	99/59612	WO		1999-11-25	Gevas et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10611582
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name		
Attorney Docket Number	065478-0205	

	18	99/66919	WO		1999-12-29	Ohannesian et al.		<input type="checkbox"/>
	19	00/16750	WO		2000-03-30	Pettersson et al.		<input type="checkbox"/>
	20	00/27366	WO		2000-05-18	Bergstrand et al.		<input type="checkbox"/>
	21	00/50007	WO		2000-08-31	Patel et al.		<input type="checkbox"/>
	22	00/50037	WO		2000-08-31	Garvey et al.		<input type="checkbox"/>
	23	00/51583	WO		2000-09-08	Rubin et al.		<input type="checkbox"/>
	24	00/69438	WO		2000-11-23	Rumsey et al.		<input type="checkbox"/>
	25	00/71122	WO		2000-11-30	Malcolm		<input type="checkbox"/>
	26	00/72838	WO		2000-12-07	Eek et al.		<input type="checkbox"/>
	27	01/03707	WO		2000-12-14	Mandel et al.		<input type="checkbox"/>
	28	01/16750	WO		2001-03-08	West et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10611582
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name		
Attorney Docket Number	065478-0205	

	29	01/19330	WO		2001-03-22	DeBony et al.		<input type="checkbox"/>
	30	01/37808	WO		2001-05-31	Patel et al.		<input type="checkbox"/>
	31	4432262	DE		1995-07-20	Denecke		<input type="checkbox"/>
	32	0426479	EP		1994-02-16	Goldman et al.		<input type="checkbox"/>
	33	2105193	GB		1983-03-23	Marriott et al.		<input type="checkbox"/>
	34	2105588	GB		1983-03-30	Brittain et al.		<input type="checkbox"/>
	35	2120938	GB		1983-12-14	Ezer et al.		<input type="checkbox"/>
	36	P2000-26296	JP					<input type="checkbox"/>
	37	00/51584	WO		2000-09-08	Rubin et al.		<input type="checkbox"/>
	38	94/25070	WO		1994-11-10	Astra Aktiebolag		<input type="checkbox"/>
	39	00/74654	WO		2000-05-31	Byk Gulden		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10611582
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name		
Attorney Docket Number	065478-0205	

40	02/45692	WO		2001-05-12	Byk Gulden		<input type="checkbox"/>
41	02/22108	WO		2002-03-21	Chih Ming Chen		<input type="checkbox"/>
42	19925710	DE		2000-12-14	Gulden et al.		<input type="checkbox"/>
43	00/26185	WO		2000-05-11			<input type="checkbox"/>
44	747293	GB		1956-04-01	Abbott Labs		<input type="checkbox"/>
45	0264259	EP		1988-04-01	Kouchiwa et al.		<input type="checkbox"/>
46	745493	GB		2007-10-18	MacLeans Ltd.		<input type="checkbox"/>
47	94/02140	WO		1994-02-03	Yoshito Mi Pharmaceuticals Industries Ltd.		<input type="checkbox"/>
48	97/25030	WO		1997-07-17	Astra Aktiebolag		<input type="checkbox"/>
49	11-110462	JP		1997-10-01	Eisai Co. Ltd.		<input type="checkbox"/>
50	2358136	GB		2001-07-18	DeMontfort Univ.		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10611582
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	
Attorney Docket Number	065478-0205

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	File history of EP Patent Application No: 0426479B1 including the following: European patent application as filed, European search report of February 22, 1991, First Office Action of August 10, 1992 and applicant's reply of December 3, 1992, Communication under Rule 51(4) EPC of February 17, 1993, Applicant's letter of July 30, 1993, Decision to grant a European patent pursuant to Article 97(2) EPC of January 6, 1994 including the non-patent references cited, Communication of notices of opposition (Rule 57(1) EPC) of December 22, 1994, Communication of	<input type="checkbox"/>
	2	Search Results for NSAIDS in Combination with Proton Pump Inhibitors-performed in 2001	<input type="checkbox"/>
	3	Search Results for Proton Pump Inhibitors and NSAIDS co-administered - performed in 2001	<input type="checkbox"/>
	4	WILSON INGALILL ET AL.: "Management of gastroduodenal ulcers and gastrointestinal symptoms associated with nonsteroidal anti-inflammatory drug therapy: A summary of four comparative trials with omeprazole, ranitidine, misoprostol and placebo" Current Therapeutic Research, December, 2001, pp. 835-850, Vol. 62, No. 12	<input type="checkbox"/>
	5	ROTE LISTE SERVICE: "Rote Liste 2000," 2000, Rote Liste Service, GmbH, Frankfurt, DE A.M. XP002222579	<input type="checkbox"/>
	6	ROTE LISTE SERVICE: "Rote Liste 2000," 2000, Rote Liste Service, GmbH, Frankfurt, DE A.M. XP002222580	<input type="checkbox"/>
	7	PHILLIPS, JEFFREY O. ET AL., "A Prospective Study of Simplified Omeprazole Suspension for the Prophylaxis of Stree-Related Mucosal Damage," Crit. Care Med., 1996, pp. 1793-1800, Vol. 24 No. 11	<input type="checkbox"/>
	8	LANDES, B. DELHOTAL ET AL., "Clinical Pharmacokinetics of Lansoprazole," Clin. Pharmacokin., 1995, pp. 458-470, Vol. 28, No. 6	<input type="checkbox"/>
	9	SHARMA, V.K. ET AL., "The Effects on Intragastric Acidity of Per-Gastrostomy Administration of an Alkaline Suspension of Omeprazole," Aliment. Pharmacol. Ther., 1999, pp. 1091-1095, Vol. 13	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10611582
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name		
Attorney Docket Number	065478-0205	

10	SHARMA, V.K. ET AL., "Oral pharmacokinetics of Omeprazole and Lansoprazole After Single and Repeated Doses as Intact Capsules or as Suspensions in Bicarbonate," Aliment. Pharmacol. Ther., 2000, pp. 887-892, Vol. 14, No. 7	<input type="checkbox"/>
11	SHARMA, V.K. ET AL., "Simplified Lansoprazole Suspension - A Liquid Formulation of Lansoprazole Effectively Suppresses Intragastric Acidity When Administered Through a Gastrostomy" Am. J. Gastroenterology, August 1999, pp. 1813-1817, Vol. 94, No. 7	<input type="checkbox"/>
12	LEWIS, ET AL., "The Physical and Chemical Stability of Suspensions of Sustained-Release Diclofenac Microspheres" J. Microencapsulation, Sept. 1, 1998, pp. 555-567 Vol. 15, No. 5	<input type="checkbox"/>
13	SHARMA, V.K. ET AL., "The Pharmacodynamics of Lansoprazole Administered via Gastrostomy as Intact, Non-Encapsulated Granules," Aliment. Pharmacol. Ther., 1998, pp. 1171-1174, Vol. 12,	<input type="checkbox"/>
14	SHARMA, V.K., "Comparison of 24-hour Intragastric pH Using Four Liquid Formulations of Lansoprazole and Omeprazole," Am. J. Health Syst. Pharm., Dec. 1, 1999, Vol. 56 Supp. 4.	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10611582
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	065478-0205

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	<i>Myriah M. Gambrell-Glean</i>	Date (YYYY-MM-DD)	2007 - 11 - 27
Name/Print	Myriah M. Gambrell-Glean	Registration Number	46,720

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.